R2 ImageChecker®

Understanding R2 ImageChecker® 9.1

MAN-00934 Rev 002

HOLOGIC®

CLARITY OF VISION

Mammography

Understanding R2 ImageChecker® 9.1

PN MAN-00934 Rev 001

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R2 ImageChecker® is a software algorithm used for analyzing mammography images. The software was originally developed by R2 Technology, and is now available as a licensed option with Hologic's R2 Cenova™ digital mammography server.

The R2 Cenova server provides a second application, R2 Quantra™, which is used for volumetric assessments of breast tissue. For more information, refer to the manual *Understanding Quantra 1.1*. (Quantra is not available in the United States.)

The information in this manual is intended to serve as a reference for radiologists and clinic personnel who need to understand how computer-aided detection (CAD) can be integrated into their practices.

1.1. Intended Use

ImageChecker is a software application intended to identify and mark regions of interest on routine screening and diagnostic mammograms to bring them to the attention of the radiologist after the initial reading has been completed. ImageChecker assists the radiologist in minimizing observational oversights by identifying areas on the original mammogram that may warrant a second review.

1.2. Resources Available

In addition to this manual, the following resources are available to assist you when working with ImageChecker and the R2 Cenova server.

- **R2 Member Center:** This website provides quick access to electronic (pdf) versions of Hologic | R2 manuals and training materials. You can find the R2 Member Center by visiting the Hologic website (www.hologic.com). See the R2U flyer that accompanies this product for instructions on accessing the R2 Member Center.
- **Manuals:** The manuals for the R2 Cenova server and its applications are listed below:
  - *Understanding R2 ImageChecker*
  - *Understanding R2 Quantra*
  - *R2 Cenova User Manual*
  - *R2 Cenova Service Manual*
  - *R2 Cenova Release Notes*
  - *R2 Cenova DICOM Conformance Statement*
  - *R2 Cenova Cybersecurity Best Practices*
  - *R2 Cenova IHE Integration Statement*

  You can obtain additional copies of printed manuals through your Hologic Account Manager. The DICOM Conformance Statement and Cybersecurity Best Practices documents are available at www.hologic.com.
- **Training:** The Hologic Applications team is available to train your staff, should you feel they need additional training. To purchase additional personalized instruction, contact your Hologic Account Manager.
- **Technical Support and Service:** For support in North America contact:

  Toll Free: +1.866.243.2533 (+1.866.CHECKED)
  Email: r2support@hologic.com
  Hours: Monday – Friday, 6:00 AM – 5:00 PM, PT (GMT –8:00)
  Website: www.hologic.com

  For support in Europe, South America, or Asia, contact your local dealer or distributor.

1.3. Warnings and Precautions

⚠ ***Note:*** *For Warnings and Cautions related to the installation, operation, and maintenance of the R2 Cenova server, refer to the* R2 Cenova User Manual.

- The radiologist should base interpretation only on diagnostic-quality images and not depend on ImageChecker CAD marks for interpretation.
- The device is a detection aid, not an interpretative aid. ImageChecker CAD marks should be activated only after the first reading.
- The device does not enhance what the user sees; rather it helps to identify regions on mammograms that should be re-examined.
- The ImageChecker software marks calcification features with triangles (Calc marks) and mass features with asterisks (Mass marks). The software marks mass and calcification features that occur at the same location on the image with pointed crosses (Malc marks). These features may not represent cancer, and the skill of the user is still required for proper interpretation of the marked areas.
- EmphaSize (variable-size) marks – Sites may choose to display prominence detail, in which case the size of a Calc, Mass, or Malc mark is proportional to the ranking of the feature by the algorithm. The marked features may not represent cancer, and the skill of the user is still required for proper interpretation of areas marked by the device.
- During routine interpretation of mammograms and results produced by ImageChecker CAD, Hologic recommends use of a mammography workstation that has been FDA-approved, recently calibrated, and employs a CAD marking schema authorized by Hologic.
- ImageChecker software does not identify all areas that are suspicious for cancer.

  – The software does not mark all lesions and a user should not be dissuaded from working up a finding if the software fails to mark that site.

  – The software is not designed to detect changes from prior mammograms.

  – The software is not designed to detect skin thickening or nipple retractions.

  – Conditions of the breast that diminish mammographic sensitivity, such as density of normal tissue, also diminish the sensitivity of the software.

  – The software is more sensitive for detection of calcifications than masses, and the sensitivity depends on the site-specific operating points chosen. For sensitivity values, see '3.9. CAD Operating Points'. In addition to not marking all masses, the algorithm has a lower sensitivity for masses greater than 2.5 cm in diameter.

  – Individual practice patterns may influence results obtained when using ImageChecker CAD. Therefore, each facility and radiologist should carefully monitor the results that the software has on their practice of mammography in order to optimize its effectiveness.
- For images with breast implants, send only Implant Displaced views to the system. Images with more than 2.5 cm (1 in) of the breast implant appearing on the image may not be processed correctly.

- The performance of the software has not been characterized for special diagnostic views (e.g., magnified views or spot-compressed views).
- Images of partial views of the breast that are not correctly identified as such, may be processed by the software, although the software has not been designed for that purpose.
- On rare occasions for a lesion on or near the pectoral muscle, the system may report a negative value for the chest wall distance.

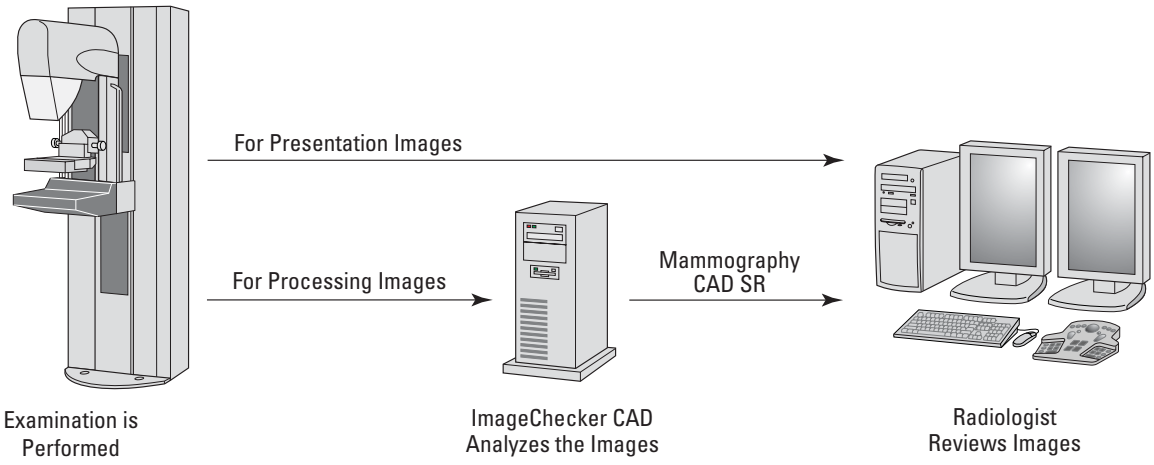
1.4. Overview of ImageChecker CAD

The R2 Cenova server configured with ImageChecker software analyzes digital mammography images produced by full-field digital mammography (FFDM) systems. The proprietary ImageChecker algorithm identifies regions of interest, which can include clusters of bright spots (suggestive of calcification clusters), and dense regions with or without radiating lines (suggestive of masses or architectural distortions). The server generates results in the form of Mammography CAD SR (Structured Report) objects that include CAD marks and other data identifying and characterizing the regions of interest. At the review workstation, the results are matched with the digital mammography images produced by the FFDM system.

After making an initial interpretation from the original diagnostic-quality images, the radiologist displays the ImageChecker results and chooses whether or not to reinspect the marked regions on the original images. The ImageChecker algorithm marks visually perceptible structures that have some of the generally accepted geometric characteristics of calcifications or masses. The marked areas may be something other than an actual abnormality, which is generally recognized by the radiologist upon a second review of the original images.

⚠ ***Note:*** *The appearance of the images on the workstation is dependent upon the acquisition modality and the workstation's display capabilities, and is not affected by the ImageChecker software.*

The R2 Cenova server and the ImageChecker algorithm are designed for sites that process only digital mammography images; the server does not scan films or support CAD with analog (film) mammograms. For information on systems that perform film-screen CAD, contact your Hologic Account Manager.



Workflow with ImageChecker CAD

1.5. Benefits of ImageChecker CAD

The interpretation of mammograms is challenging. Normal breast tissue varies widely among women, even for the same woman over time or at different times of the month. The radiologist also has to balance the need for accurate detection with the need to limit the number of unnecessary procedures. The combination of viewing a large number of cases, radiologist fatigue, the complex image of the breast structure, and the subtle nature of certain observable characteristics of the disease can result in false-negative readings. In fact, studies show that half of undetected cancers are missed due to observational oversights. The prevalence of observational oversights is not strongly related to experience and may be inevitable with human observers.

ImageChecker CAD functions like a spellchecker for medical images. It is designed to help radiologists in reducing the number of false-negative readings due to observational oversight by drawing their attention to areas that may warrant a second review. Retrospective clinical studies using the film-based ImageChecker algorithm have shown that use of ImageChecker CAD can result in earlier detection of up to 23.4% of the cancers currently detected with screening mammography in those women who had a prior screening mammogram 9–24 months earlier. Early detection is the key to higher survival rates, better prognosis, and lower treatment costs.

1.6. Devices Used with ImageChecker CAD

All systems with ImageChecker include the following devices:

- Digital mammography image acquisition system(s)
- R2 Cenova server configured with the ImageChecker option
- Diagnostic review workstation or PACS

The ImageChecker software can accept digital mammography images from a supported Full-Field Digital Mammography (FFDM) system or a PACS (picture archiving and communication system). Once received, the server performs the CAD algorithm processing and sends the study results (CAD marks and related data) to one or more devices such as Hologic's SecurView$_{DX}$ diagnostic workstation or a PACS for storage.

The system devices are connected by a computer network and can be in the same room, different rooms, the same building, different buildings, or even different cities. The server can send results to several different output devices.

Image Acquisition Systems

ImageChecker processes mammography images originating from the following image acquisition systems:

- Hologic Selenia
- GE Senographe 2000D, GE Senographe DS, and GE Senographe Essential
- Siemens Mammomat Novation^{DR}

In addition, ImageChecker processes mammography images originating from the following image acquisition systems:

- Selenia Dimensions (2D Only)
- Fuji CRm

⚠ ***Important!*** *The FDA has not approved the use of ImageChecker 9.1 with images originating from the Selenia Dimensions and Fuji CRm systems in the United States.*

R2 Cenova does not process mammography images originating from the Fischer SenoScan system.

R2 Cenova can process images originating from up to four image acquisition devices. The DICOM header for each image includes an identifier (e.g., a serial number) that indicates the device from which the image originated. Each image-acquisition device is mapped to an input port on the server. For each R2 Cenova server, you can purchase licenses for up to four ImageChecker input ports.

R2 Cenova Server

The ImageChecker software is supplied on the R2 Cenova server, a high-performance computer that can be located in any non-patient environment, provided it is connected to the mammography network. The server receives and processes digital mammography images and supports up to four ImageChecker ports (each port licensed to a specific detector).

R2 Cenova integrates easily into the clinical workflow. Following a mammography examination, the FFDM system sends digital mammography images to the clinic's review workstation, PACS, and the R2 Cenova server. The server accepts and processes each For Processing image and sends the results to the review workstation and PACS.

For more information on the server, refer to the *R2 Cenova Server User Manual*.

Diagnostic Review Workstations and PACS Devices

Mammography CAD SR results produced by R2 Cenova can be sent to a variety of PACS devices and diagnostic review workstations (including SecurView$_{DX}$ available from Hologic, Inc.).

For diagnostic review workstations and PACS devices that do not support Mammography CAD SR, but do support DICOM 6000 overlays, Hologic's DICOM 6000 Interface server can be used to convert Mammography CAD SR objects. For more information, contact your Hologic Account Representative.

1.7. ImageChecker Features

Each R2 Cenova server with ImageChecker software is delivered with a number of licensed features in place. Upon installation, the Hologic | R2 field service engineer will tailor the software to enable or disable selected features based on the preferences of site personnel. Thereafter, your Hologic | R2 representative can help you add new licenses and enable or disable features as needed.

Input Ports

The R2 Cenova server can process images originating from up to four FFDM systems. The DICOM header for each image includes an identifier (e.g., a serial number) that indicates the device from which the image originated. Each image-acquisition device is mapped to an input port on the server.

For each R2 Cenova server, you can purchase licenses for up to four ImageChecker input ports. Similarly, you can obtain licenses for up to four Quantra input ports.

The server can also process images sent from any number of PACS devices, as long as the images originated from one of the licensed FFDM systems.

Citra Core

The standard set of ImageChecker features is included in the Citra™ Core license group, which includes the following features:

- RightOn™ CAD Marks
- EmphaSize™
- PeerView Digital™
- LesionMetrics™

EmphaSize, PeerView Digital, and LesionMetrics are exclusive Hologic | R2 features supported by some diagnostic review workstations. When these features are licensed, the ImageChecker software includes extra CAD information in the Mammography CAD SR output. When viewed at the workstation, the results help radiologists understand better why a region of interest received a CAD mark.

The Citra Core features are discussed in the following pages. For additional information, see 'Part 3: Algorithm Description'.

⚠ ***Important!*** *Display of results from each ImageChecker feature depends upon several factors, in particular:*

- *The feature must be licensed and enabled on the R2 Cenova server.*
- *The workstation must be equipped with software that can interpret the output produced by the server.*

Individual Citra Core features can be disabled either at the R2 Cenova server or, in most cases, at the diagnostic workstation. Some workstations can interpret only a subset of Citra Core features. Consult with your workstation vendor concerning availability and integration of ImageChecker features with your workstation.

RightOn CAD Marks

The ImageChecker software provides three types of RightOn CAD marks (Mass, Calc, and Malc) that can appear in the results shown on the review workstation. You can choose to display any or all of the three types of marks. Each mark identifies a region of interest for the radiologist to review.

Calc – Marks regions suggestive of calcifications.

Mass – Marks regions suggestive of masses or architectural distortions.

Malc – Marks regions where Calc and Mass marks are coincident.

EmphaSize

The server is configured by default to convert the CAD marks to EmphaSize marks. The feature allows the review workstation to display marks of variable size that correlate to feature significance. When the algorithm determines that a region is more significant, the CAD mark appears larger, indicating that the region should receive more emphasis from the radiologist. EmphaSize marks can be disabled if clinic staff choose not to use them. For more information see '3.3. EmphaSize Marks'.

PeerView Digital

PeerView Digital enables the radiologist to understand better why a region of interest was marked. On advanced review workstations such as Hologic's SecurView$_{DX}$, PeerView Digital highlights physical features found by the algorithm. For more information see '3.4. PeerView Digital'.

LesionMetrics

LesionMetrics provides data computed by ImageChecker CAD for each region of interest marked by the algorithm. Depending upon the type of lesion, the software can compute metrics such as lesion size, distance to nipple, distance to chest wall, degree of spiculation, calcification contrast, number of calcifications, and mass density. For more information see '3.5. LesionMetrics'.

Operating Points

The ImageChecker algorithm offers three operating points (i.e., CAD algorithm thresholds) to accommodate differing radiologist preferences: operating point 0, which emphasizes specificity (a low false-mark rate), operating point 1, which is a balanced intermediate point, and operating point 2, which emphasizes sensitivity. The algorithm performance for each of the operating points is summarized below:

Operating Point	0	1	2
Calcification Sensitivity	95%	96%	97%
Mass Sensitivity	83%	88%	90%
False Marks per Case	1.0	1.5	2.0

When your system is installed, the server is configured to use operating point 1 for masses and operating point 2 for calcifications. You can choose other settings, or your service representative can change the operating points at a later time. For new customers, Hologic | R2 recommends using the default settings for the first four to six weeks to allow you to become familiar with the R2 marks and algorithm behavior.

Hologic's ImageChecker algorithm provides the medical-imaging industry's highest sensitivity at any given false-mark rate. ImageChecker CAD was the first computer-aided detection software approved by the FDA for full-view diagnostic and screening mammograms. Since that first approval, the ImageChecker software has been refined many times, resulting in an algorithm that is highly sensitive with few false marks. For more information, see '3.9. CAD Operating Points'.

Part 2: Data Inputs and Outputs

- 2.1. System Data Flows
- 2.2. CAD Inputs and Supported Views
- 2.3. Image and Case Processing
- 2.4. CAD Outputs

Part 2 explains how information flows through systems with ImageChecker CAD, the supported mammography views, and the result formats.

2.1. System Data Flows

This section describes the flow of data among the various Hologic | R2 devices. Mammography systems may have different configurations, depending upon the devices installed at your site:

- Digital CAD Systems
- Digital CAD with DICOM 6000 Overlay
- Digital and Film-Based CAD with DigitalNow

Digital CAD Systems

To follow the data flows, refer to the diagram on the following page.

Image Acquisition Device(s)

1, 2, 3: FFDM systems can be configured to send Digital Mammography X-Ray images to any device that conforms to the Digital Imaging and Communications in Medicine (DICOM) standard. The FFDM device sends two types of images, *For Processing* images to the R2 Cenova server, and *For Presentation* images to the diagnostic review workstation(s) and PACS.

⚠ ***Note:*** *The DICOM standard specifies two classes of archivable digital mammography images with the following designations:*

- *Digital Mammography X-Ray Image Storage – For Processing images*
- *Digital Mammography X-Ray Image Storage – For Presentation images*

R2 Cenova Server

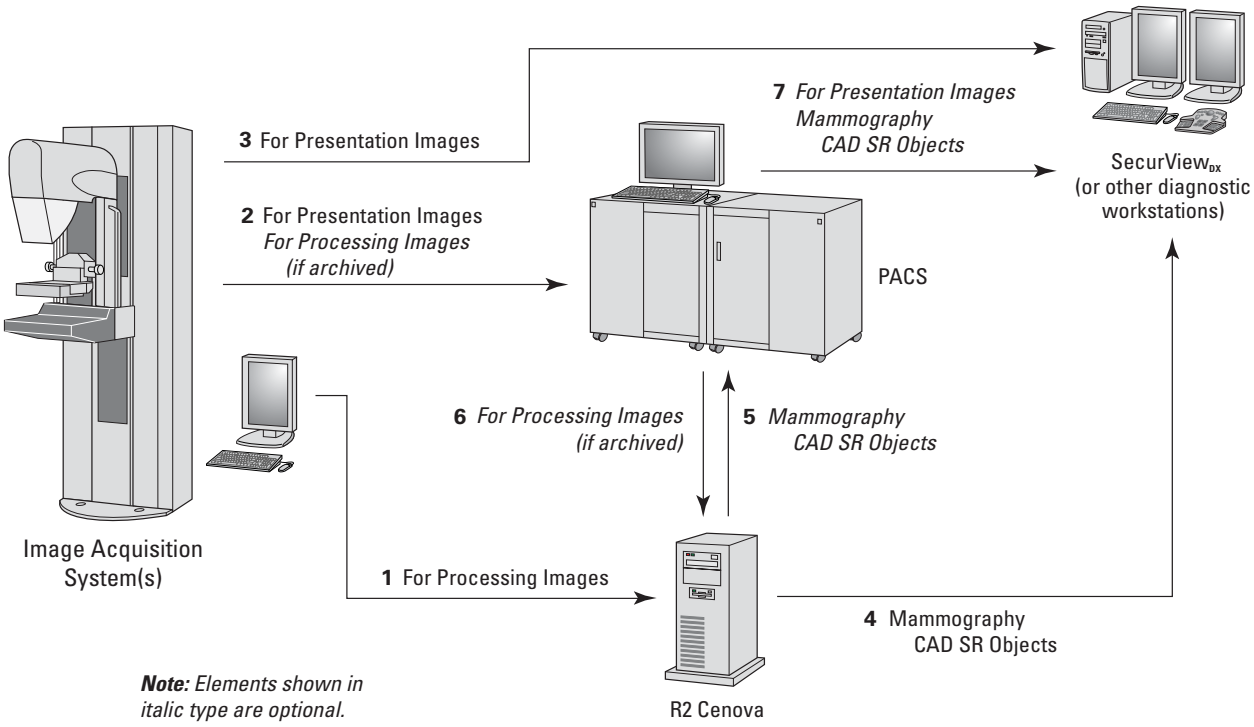
4, 5: R2 Cenova servers send results (Mammography CAD SR objects) to one or more diagnostic review workstation(s) and/or PACS devices simultaneously.

Diagnostic Review Workstation(s) and PACS

4, 7: The review workstation(s) are configured to receive the For Presentation images and CAD results, which are then reviewed by the radiologist.

6, 7: The PACS can be configured to send:

- For Processing Digital Mammography X-Ray images to R2 Cenova (6), which processes the images and distributes the CAD results according to its configuration, and/or
- CAD results and/or For Presentation Digital Mammography X-Ray images to the review workstations (7).



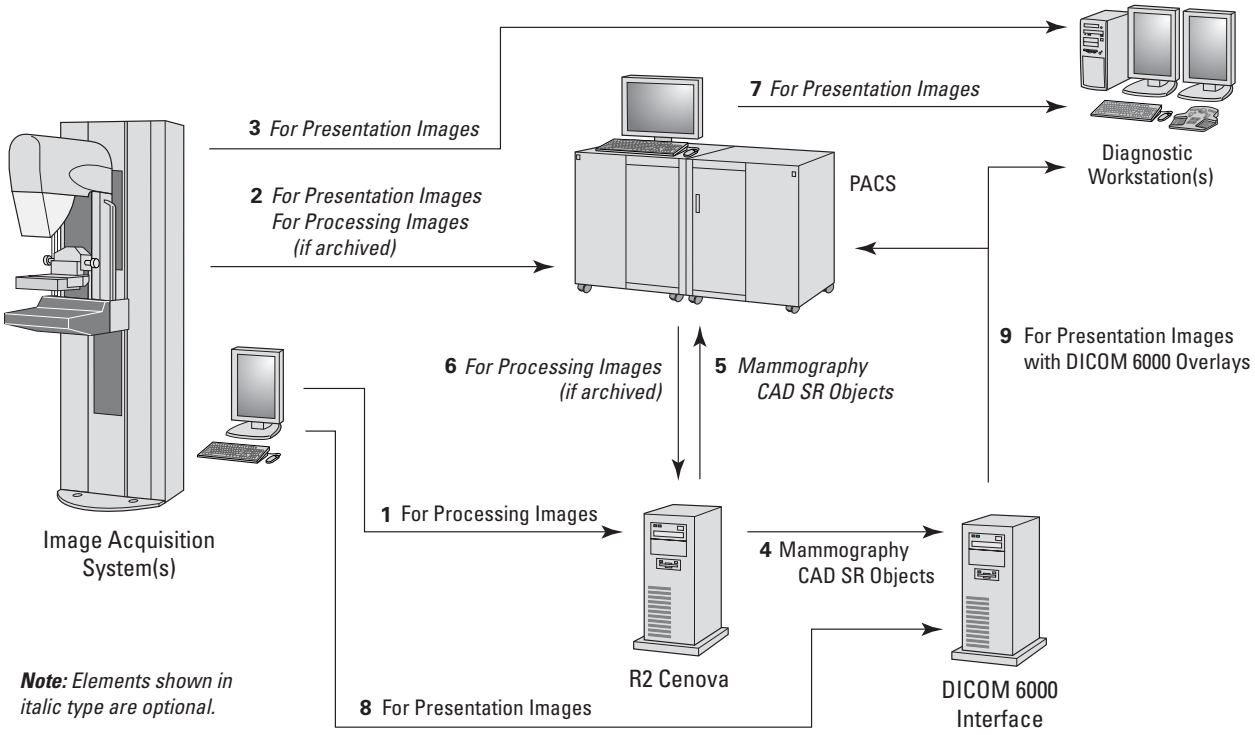
Digital CAD System

Digital CAD with DICOM 6000 Overlay

Typically, diagnostic review workstations and PACS devices support the Mammography CAD SR results format. If the review workstation or PACS does not support Mammography CAD SR, but does support DICOM 6000 overlays, a supplementary interface computer can be installed.

The DICOM 6000 Interface server creates a copy of the For Presentation image with an overlay containing the CAD results that can be viewed on the diagnostic workstation. (Refer to paths 4, 8, and 9 in the diagram below. The earlier diagram provides information on data flows 1–7.)

For more information about the Hologic DICOM 6000 interface option, contact your Hologic Account Representative.



Digital CAD System with DICOM 6000 Interface

Digital and Film-Based CAD with DigitalNow

Some facilities with analog (film-based) mammography systems, or those with large film libraries may wish to acquire one of Hologic | R2's film-scan systems (R2 DMax or R2 LS). With these systems, the scanned films can be analyzed using ImageChecker CAD, or they can be converted to archivable digital images using Hologic | R2's DigitalNow feature.

To follow the data flows, refer to the diagram on the next page. The earlier diagrams provide information on data flows 1–7.

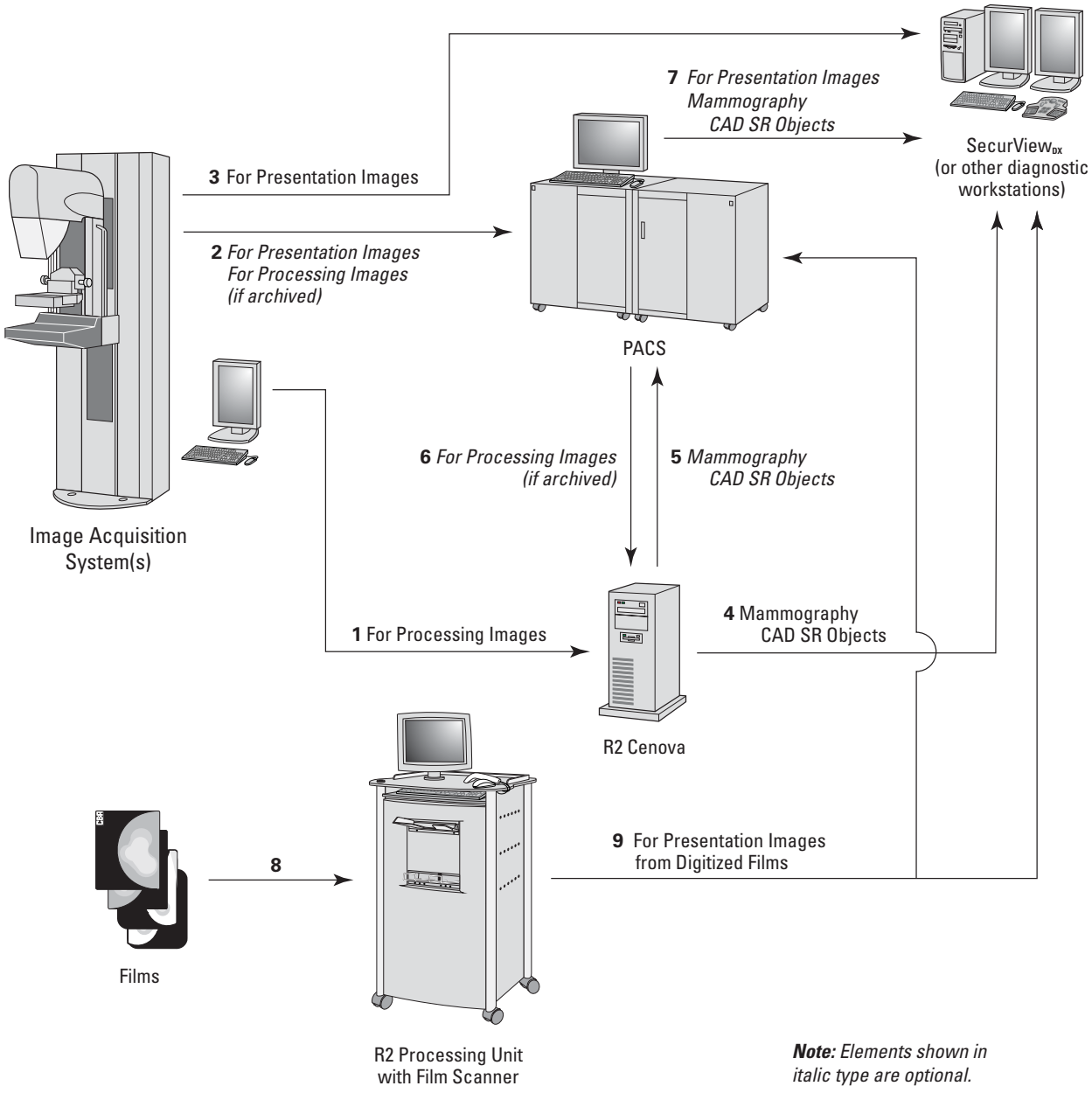
Films

8: Film priors are fed into the processing unit with film scanner, which scans (digitizes) the films and processes the resulting images.

Processing Unit with Film Scanner

9: The R2 processing unit with film scanner can be configured to send ImageChecker results (processed from digitized film images) and/or the For Presentation Digital Mammography X-Ray images themselves to a PACS or review workstation.

When scanning films for digital review, sites need the ability to retrieve patient information in order to add the required identification information to the resulting Digital Mammography X-Ray images. Sites can use the R2 Patient ID feature to either enter patient data manually or retrieve the data from a PACS or RIS (Radiology Information System).



Digital CAD with DigitalNow

2.2. CAD Inputs and Supported Views

The ImageChecker software analyzes digital mammography images that conform to the Digital Imaging and Communications in Medicine (DICOM) standard.

If your system has the ImageChecker license, all images are CAD-processed if the views are supported by the software. The following table lists the views and view modifiers supported by the ImageChecker software:

Supported DICOM Views and View Modifiers		ACR MQCM 1999* View Label
Screening Views	Cranio-Caudal	CC
	Medio-Lateral Oblique	MLO
Equivalent Views	Medio-Lateral	ML
	Cranio-Caudal Exaggerated	XCC
	Cranio-Caudal Exaggerated Laterally	XCCL
	Cranio-Caudal Exaggerated Medially	XCCM
Reversed Equivalent Views	Latero-Medial	LM
	Latero-Medial Oblique	LMO
	Cranial-Caudal From Below	FB
	Superolateral to Inferomedial Oblique	SIO
View Modifiers	Axillary Tail (modifies MLO views only)	AT
	Rolled Inferior	…RI
	Rolled Lateral	…RL
	Rolled Medial	…RM
	Rolled Superior	…RS
	Implant Displaced	…ID
	Tangential	TAN

The ImageChecker software does *not* support the following view modifiers:

Unsupported View Modifiers	ACR MQCM 1999* View Label
Cleavage (modifies CC views only)	CV
Magnification	M…
Spot Compression	S…

*American College of Radiology Mammography Quality Control Manual 1999

Images with Breast Implants

The ImageChecker software does attempt to process images with breast implants. For images with breast implants, send only Implant Displaced views to the system. Images with more than 2.5 cm (1 in) of the breast implant appearing on the image may not be processed correctly.

2.3. Image and Case Processing

During processing, the ImageChecker software analyzes each received image, as long as the view is supported by the software. The algorithm searches for patterns suggestive of calcification clusters and masses or architectural distortions, characterizes each suspected lesion, and finally determines the location and numbers of CAD marks for the image. This initial analysis is known as *image processing*.

The R2 Cenova server reads the DICOM header of each received image and groups successive images from a single patient into a study. There is no specified limit to the number of images that can be included in a study. However, for many patients, a study consists of the four screening views:

- LCC – Left Cranio-Caudal
- RCC – Right Cranio-Caudal
- LMLO – Left Medio-Lateral Oblique
- RMLO – Right Medio-Lateral Oblique

As an additional step when a study includes two or more views, the ImageChecker algorithm selects up to four views and compares the images to each other in a process known as *case processing*. By checking for similarities and differences between the images, the algorithm can further refine its findings for the four selected views. When case processing is complete, the ImageChecker algorithm compiles the results into a single Mammography CAD SR object that includes results for the images selected for case processing and the remaining images.

As a result of the case processing analyses, ImageChecker may produce a different set of CAD marks for an individual image than when the image is part of a case. When ImageChecker applies the more sophisticated case processing rules it may add or discard marks. For example:

- Some large masses are marked only when the image is part of the bilateral asymmetry analysis used for case processing.
- Some marks may be discarded when the image is subjected to the mark capping limitations used for case processing). For more information, see 'Limiting the Number of Marks' in '3.2. RightOn CAD Marks'.

For more information about image and case processing, see '3.7. Detecting Calcifications' and '3.8. Detecting Masses'.

Selecting Images for Case Processing

The ImageChecker algorithm uses the following criteria to determine which images will be case-processed:

- If a study includes one image for each of the four screening views or their equivalents, then all images are case-processed.
- When a study includes multiple images of the same view and laterality (e.g., two RCC views), case processing is performed on the *last* image produced by the FFDM device for each of the four screening views or their equivalents. The image-acquisition time is included in the DICOM header for each image. (Refer to the diagram on the following page.)
- If a study does not include one or more of the four screening views, then the equivalent views (or the reversed equivalent views) are case-processed, if they are

present. Screening views are given preference over equivalent views, which in turn are given preference over reversed equivalent views.

- The view modifiers, if present, do not affect which images are selected for case processing.
- When a study includes multiple equivalent (or reversed equivalent) views, the views selected for case processing are based on the following preference order:

Preference Order	CC Equivalent	MLO Equivalent
1	CC	MLO
2	FB	ML
3	XCC	LM
4	XCCL	LMO
5	XCCM	SIO

For example, if a study includes the four screening views plus two additional RMLO images (as is shown in the figure below), all the images are image-processed separately. However, when selecting images for case processing, the ImageChecker algorithm includes only the *last* RMLO image acquired by the FFDM device (along with the other three screening views). As is shown below, the algorithm would select the RMLO 3 image for case processing.

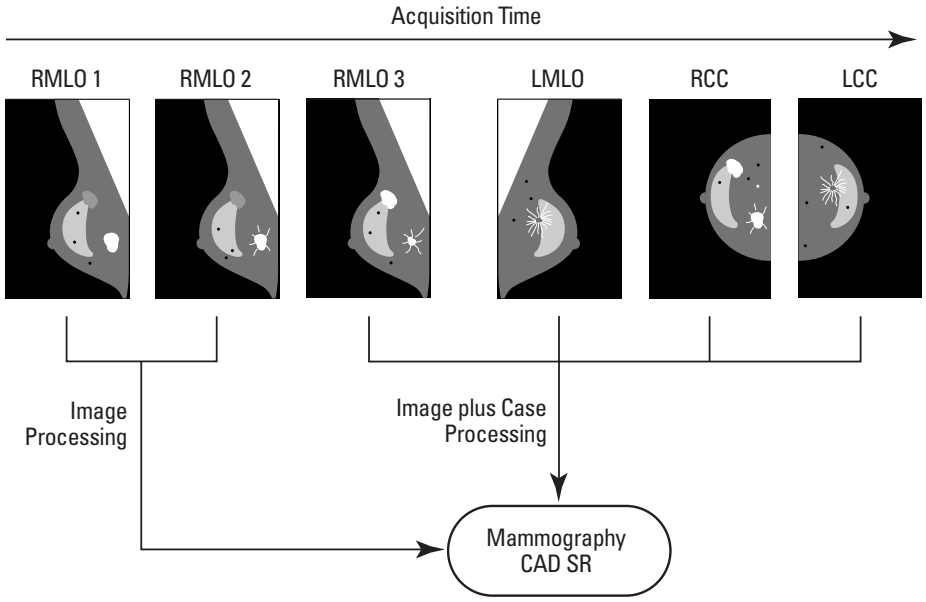


Image and Case Processing

As a further example, for a study with segmented breast views including multiple CC images, you may choose to image the anterior (ductal) region of the breast last in the sequence to ensure that that image is case-processed.

2.4. CAD Outputs

The server can be configured to send results in one or more of the following formats:

- **Mammography CAD SR 9.1** results are derived from the latest version of the ImageChecker algorithm. The 9.1 format can provide the complete range of Hologic | R2 features, depending upon the license options purchased by the site, the features that are enabled, and the capabilities of the review workstation.
- **Mammography CAD SR 5.x** provides backward compatibility with previous releases of ImageChecker 5.x products. The 5.x format provides only RightOn Calc and Mass Marks and PeerView Digital.
- **CAD Radiotherapy Structured Set (RTSS).** This CAD results format was developed specifically for GE review workstations. In earlier ImageChecker software versions (5.x and 8.1) it was labeled 'CAD DICOM Int'. This object should not be stored to PACS.

In most facilities, results produced by the R2 Cenova server are compiled into DICOM-conformant Mammography CAD SR objects. The Mammography CAD SR format is the DICOM standard format for CAD results. For more information, refer to the *R2 Cenova DICOM Conformance Statement*.

Mammography CAD SR objects are most useful when viewed with the images on an advanced workstation such as Hologic's SecurView$_{DX}$ diagnostic workstation. Most dedicated mammography workstations display the Mammography CAD SR format as overlays on the underlying images. With certain advanced mammography workstations, radiologists can work with CAD results interactively.

Although some PACS do not support Mammography CAD SR, there is increasing support for storing Mammography CAD SR objects on PACS devices. In recent years, an increasing number of PACS workstation models have been developed that can display Mammography CAD SR content, partly in response to the Mammography Image Profile released by IHE (Integrating the Healthcare Enterprise).

If the results are not archived, they can be recreated at a later time if the For Processing images have been archived. In most cases, the same results (ImageChecker CAD marks, PeerView Digital data, etc.) should be generated each time the images are reprocessed.

DICOM 6000 Overlays

For diagnostic review workstations and PACS devices that do not support Mammography CAD SR or RTSS, but do support DICOM 6000 overlays, Hologic's DICOM 6000 Interface server can be used to convert Mammography CAD SR objects (see 'Digital CAD with DICOM 6000 Overlay' on page 15). For more information, see the *DICOM 6000 Interface User Manual*, or contact your Hologic Account Representative.

Part 3: Algorithm Description

- 3.1. ImageChecker CAD Algorithm
- 3.2. RightOn CAD Marks
- 3.3. EmphaSize Marks
- 3.4. PeerView Digital
- 3.5. LesionMetrics
- 3.6. What the Algorithm Detects
- 3.7. Detecting Calcifications
- 3.8. Detecting Masses
- 3.9. CAD Operating Points

Part 3 describes the algorithm used by the ImageChecker software when analyzing mammography images.

3.1. ImageChecker CAD Algorithm

The ImageChecker algorithm looks for characteristics commonly associated with cancer – specifically, calcifications and masses (including architectural distortions). The algorithm ranks its findings by likelihood, places marks on those regions above a fixed threshold of likelihood (operating point), and then sends the results to the review workstation. The algorithm offers three operating points to accommodate differing radiologist preferences. For more information, see '3.9. CAD Operating Points'.

3.2. RightOn CAD Marks

ImageChecker provides three types of CAD marks. Each mark indicates a region of interest for the radiologist to review. There are two basic types of marks plus one composite mark, as summarized below.

Calc – Marks regions suggestive of calcifications

Mass – Marks regions suggestive of densities/masses/architectural distortions

Malc – Composite mark indicates Calc and Mass marks occurring in the same location on the image

ImageChecker CAD Marks

⚠ ***Note:*** *Not all mammography workstations can display Malc marks. Consult with your workstation vendor concerning availability and integration of ImageChecker features with your workstation.*

Limiting the Number of Marks

The software limits or 'caps' the number of CAD marks for each image and case. The actual number of CAD marks produced depends upon the individual case and the operating point selected for the CAD algorithm.

Views	Per Image Limit	Per Case Limit
Screening views (RCC, LCC, RMLO, LMLO)	3 Calc marks 2 Mass marks 2 Malc marks	8 Calc marks 4 Mass marks 4 Malc marks
Extra views	3 Calc marks 2 Mass marks 2 Malc marks	Dependent upon the number of images*

*For cases with more than four views, the maximum number of marks per case depends upon the number of images in the case.

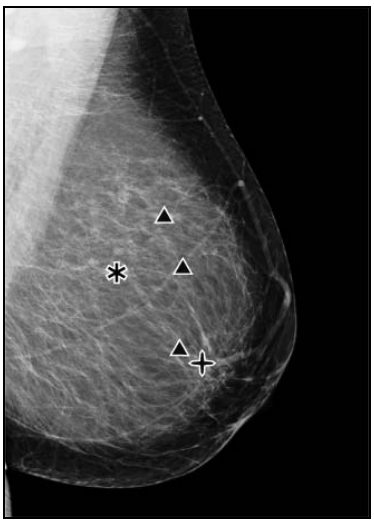
When ImageChecker processes an individual image, it may show a set of CAD marks different from the marks reported when the image is part of a case. The differences are due to the fact that ImageChecker first processes the images individually before analyzing the case. When ImageChecker applies the more sophisticated case processing rules (such as bilateral asymmetry analysis), it may discard marks for regions that are less suspicious. For more information, see '2.3. Image and Case Processing'.

3.3. EmphaSize Marks

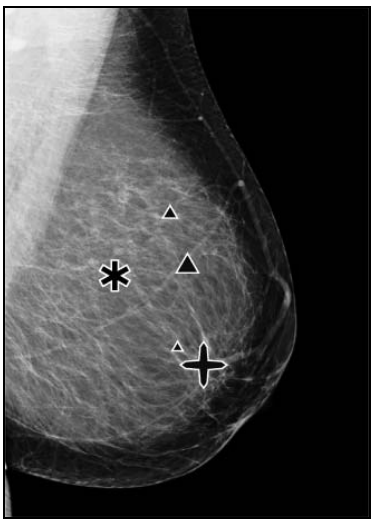
EmphaSize is an optional feature that provides variable-size CAD marks that scale according to feature significance. When the ImageChecker algorithm considers a region to be more significant, it increases the size of the EmphaSize CAD mark. The size of the mark does not correlate to the size of the lesion.

As the algorithm evaluates regions of interest, each region is given a ranking. This ranking along with the selected algorithm operating point determines whether or not the region of interest is marked with a CAD mark.

The system normally displays all CAD marks at the same size regardless of ranking. If your site has enabled the EmphaSize feature and configured the review workstation to use it, the ImageChecker algorithm adjusts the size of each mark according to its ranking. The EmphaSize feature can be disabled if you do not want to use it.



CAD without EmphaSize



CAD with EmphaSize

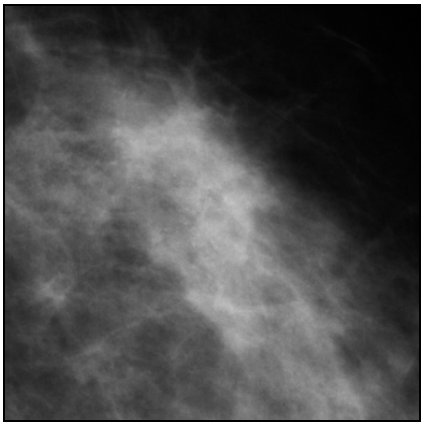
- **Calcifications:** The size of a suspected lesion is of variable significance, since small lesions may be highly significant and large lesions may be nonactionable. However, there are other key characteristics. For calcifications, the algorithm looks at characteristics such as signal intensity, number of calcifications in a cluster, shape of the calcifications (i.e., pleomorphism), and other important features to determine lesion significance.
- **Masses**: For masses, the algorithm looks at characteristics such as degree of spiculation, lesion shape, contrast to surrounding tissue, and other important features which help determine lesion significance.
- **Masses with Calcifications (Malc Marks)**: Regions containing both a mass and calcifications are suspicious and should be carefully evaluated.

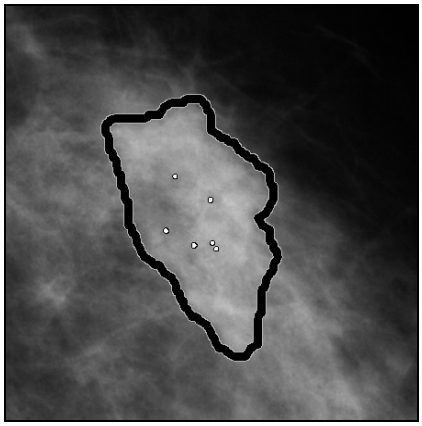
⚠ ***Note:*** *Not all mammography workstations can display EmphaSize marks. Consult with your workstation vendor concerning availability and integration of ImageChecker features with your workstation.*

3.4. PeerView Digital

PeerView Digital is an optional, licensed feature designed to help radiologists better understand why a region of interest was marked. When licensed, PeerView Digital adds graphical information to the Mammography CAD SR output. At the review workstation, the radiologist can use PeerView Digital to highlight regions of interest detected by the ImageChecker algorithm.

- **Calcifications:** PeerView Digital highlights individual calcifications in the cluster marked by the algorithm. PeerView Digital may not highlight all calcifications in a cluster, and it may show features suggestive of calcifications that are not calcifications.
- **Masses:** PeerView Digital defines and outlines the central density of the mass so the radiologist can evaluate the margin, shape, and interior characteristics of the CAD-detected mass or distortion. The outline does not generally include spiculations associated with the mass, although the shape of the central density may lead the eye to larger spicules.
- **Masses with Calcifications:** For composite Malc marks, which indicate that one or more Mass and Calc marks occur at the same location on the image, PeerView Digital highlights the calcifications and outlines the central density of the mass and/or distortion found in the CAD analysis. The same region is shown with and without a PeerView Digital Malc mark (mass with calcifications).





⚠ ***Note:*** *Not all mammography workstations can display PeerView Digital highlights. Consult with your workstation vendor concerning availability and integration of ImageChecker features with your workstation.*

3.5. LesionMetrics

LesionMetrics is an optional, licensed feature that provides data computed by the ImageChecker algorithm for each marked region of interest marked. When licensed, LesionMetrics are included as part of the Mammography CAD SR object for each image processed by the algorithm. The LesionMetrics are summarized in the following table.

LesionMetric	Description	Calc	Mass	Malc
R2 CAD Score	A number from 0 to 100 that reflects the prominence of the features detected by the algorithm for the region of interest. The higher the number the more prominent the features. The R2 CAD Score is not linearly related to probability of malignancy.	✓	✓	✓
Number of Calcifications	Number of individual calcifications detected by the algorithm at the current operating point.	✓		✓
Size (long axis)	Long axis in cm for the calcification cluster or mass.	✓	✓	✓
Distance to Nipple*	The radial distance in cm from the center of the lesion to the estimated nipple location.	✓	✓	✓
Distance to Chest Wall*	The estimated perpendicular distance in cm from the center of the lesion to the chest wall. For lesions in an upper quadrant, this metric may resolve to the perpendicular distance to the pectoral muscle, which can be reported as a negative value.	✓	✓	✓
Calcification Contrast (%)	The average difference in brightness between the individual calcifications and their immediate background normalized on a scale of 0 to 100.	✓		✓
Mass Density (%)	The average brightness of a lesion relative to its immediate background normalized on a scale of 0 to 100.		✓	✓
Degree of Spiculation (%)	A measurement proportional to the number of pixels that lie on lines pointing to a common origin inside the potential lesion, reported on a normalized scale of 0–100 containing the entire spectrum of biopsy-proven malignant masses.		✓	✓
Operating Point	The selected operating points (algorithm thresholds) for calcifications and masses.	✓	✓	✓

***Note:** The accuracy of the measurement is subject to the positioning of the patient and other factors such as confluence of tissue and radiographic exposure. In any given image the distance can be determined manually using the workstation measurement tool.

The LesionMetrics feature is implemented on a limited number of review workstations. On SecurView$_{DX}$ (version 6-0 or later) you can enable or disable any or all of the LesionMetrics. Refer to your workstation's documentation to determine whether these features are implemented and, if they are, how to use them.

3.6. What the Algorithm Detects

The ImageChecker algorithm searches an image for clusters of bright spots that are suggestive of calcification clusters, for patterns of dense regions, and for dense regions with radiating lines suggestive of masses or architectural distortions.

Calcifications

The algorithm marks:

- Clusters with three or more elements
- Elements that are at or within 3 mm of each other
- Where each element is at least 150 microns in size

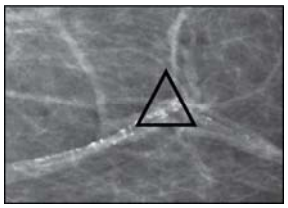
The algorithm does not mark:

- Clusters with fewer than three elements*
- Clusters where each element is separated by more than 3 mm
- Elements it considers to be of benign morphology
- Low-contrast elements
- Lead skin markers or clips

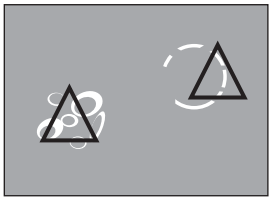
⚠ ***Note:** The algorithm marks two elements if the elements have significant contrast or shape, as defined by the cluster filter. See '3.7. Detecting Calcifications'.*

The algorithm occasionally marks:

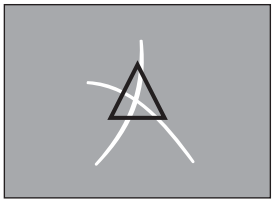
- Calcified arteries
- Cluster or rim benign calcifications
- Crossing linear tissues



Calcified Artery

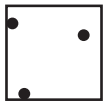


Cluster or Rim
Benign Calcifications

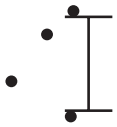


Crossing Linear
Tissues

To be considered a cluster, elements need only be at or within 3 mm of another element within the cluster, as shown next:

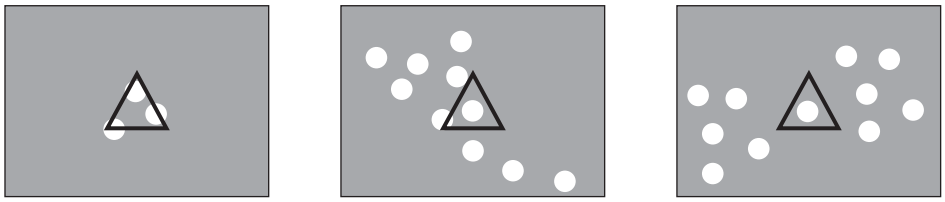


≤ 3 mm square



Each element is
at or within 3 mm

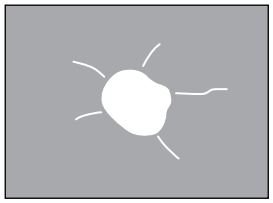
When features in the mammogram meet the ImageChecker criteria, the algorithm places a triangular CAD mark over the center of that region (not over a particular element), as is shown next:



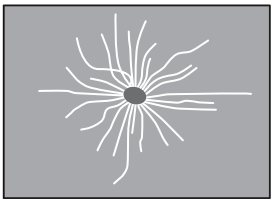
Masses/Architectural Distortions

To detect masses, the ImageChecker algorithm searches the image in a progressive manner looking for circular, dense regions and lines radiating from a common center. The algorithm marks:

- Regions suggestive of masses/architectural distortions
- Dense regions
- Regions with radiating lines



Less pronounced radiating lines but with a central mass

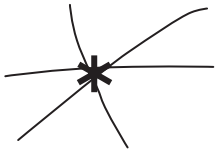


No central mass but pronounced radiating lines

The algorithm occasionally marks:

- Ducts and tissue radiating from the nipple
- Inadvertent crossing of parenchymal tissue
- Well circumscribed masses
- Lymph nodes
- Vague opacities, skin thickening, or nipple retraction

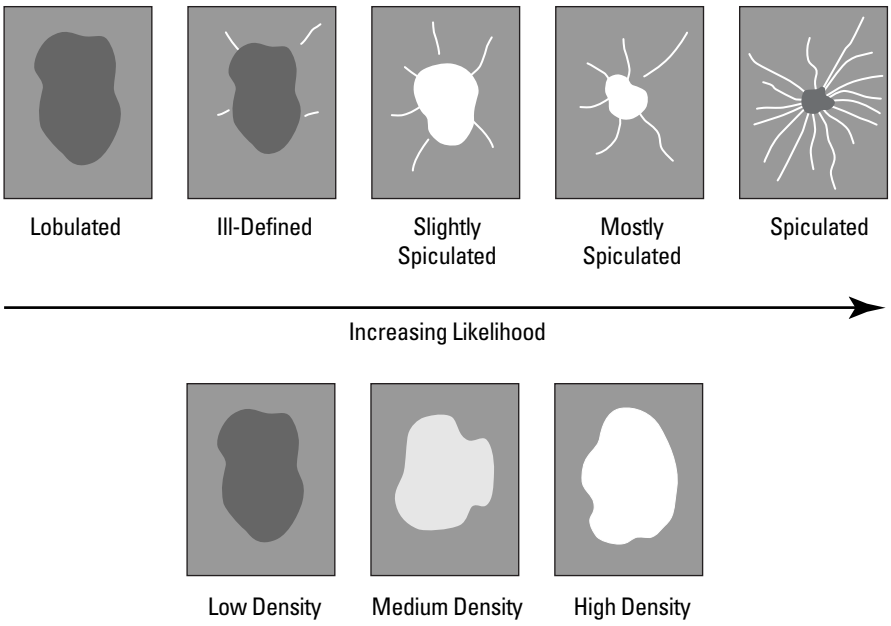
Ducts and tissue radiating from nipple



Inadvertent crossing of parenchymal tissue

The likelihood of a mass/architectural distortion being marked is affected by:

- Margin of the mass (the greater the spiculation, the more likely)
- Degree of density (the higher the density, the more likely)
- Presence of left/right breast asymmetry



When the algorithm finds patterns associated with masses, it places an asterisk at the point of maximum convergence on the image.

3.7. Detecting Calcifications

To detect calcifications, the ImageChecker algorithm performs a series of analyses.

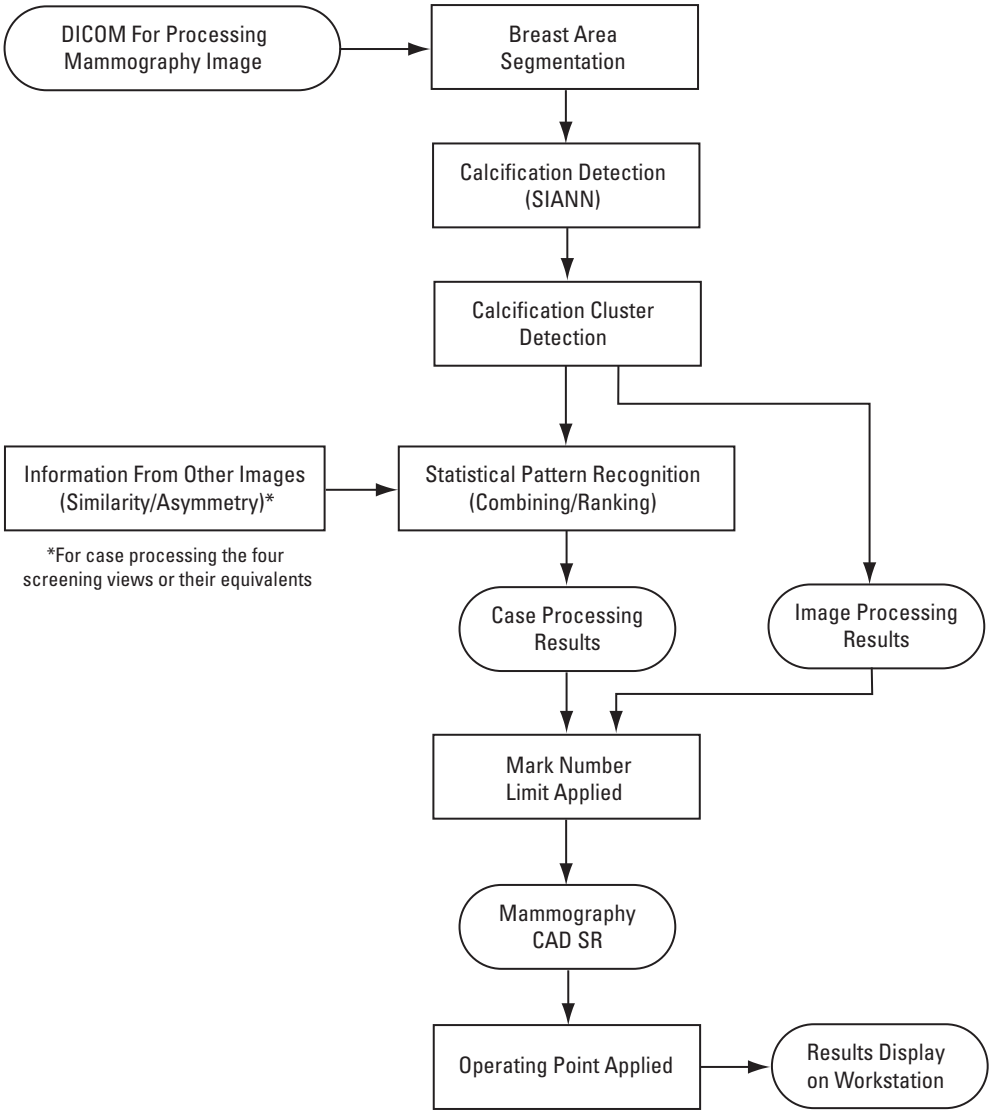
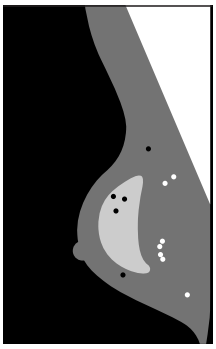

DICOM For Processing Mammography Image
Breast Area Segmentation
Calcification Detection (SIANN)
Calcification Cluster Detection
Information From Other Images (Similarity/Asymmetry)*
Statistical Pattern Recognition (Combining/Ranking)
*For case processing the four screening views or their equivalents
Case Processing Results
Image Processing Results
Mark Number Limit Applied
Mammography CAD SR
Operating Point Applied
Results Display on Workstation

Image Processing for Calcifications



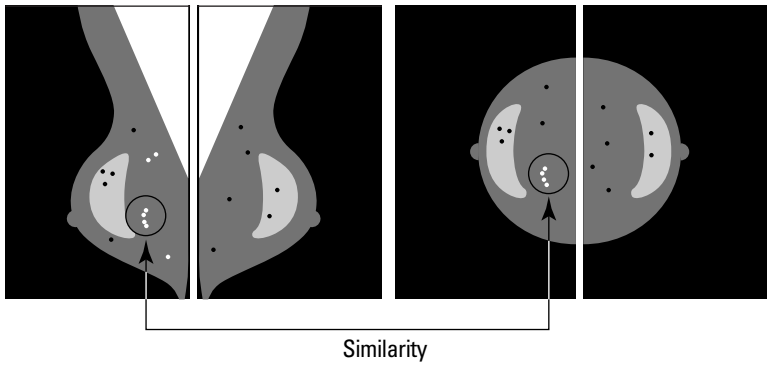
For each image, the algorithm uses two filters (artificial neural networks) to identify calcifications and their features:

- First, it runs each image through a Shift-Invariant Neural Network (SIANN), a calcification detection filter that has been optimized using R2 Technology's large training database. SIANN is a patented technology developed through more than 10 years of research at the University of Chicago.
- Then, it analyzes the resulting calcifications using a cluster filter that weights over a dozen different features, including contrast, shape, and size.

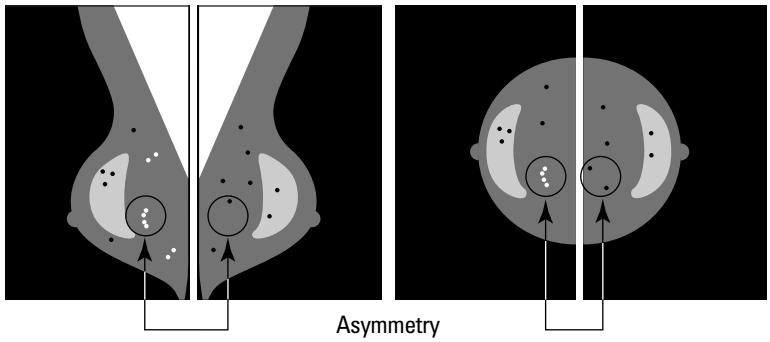
In addition, the algorithm segments the breast and identifies the location of the cluster within the breast.

Case Processing for Calcifications

In addition to processing images individually, the ImageChecker algorithm selects up to four images that represent the screening views – RCC, LCC, RMLO, and LMLO (or their equivalents). The algorithm reviews the findings from each image and looks for similarities in the findings by comparing complementary orthogonal views (for example, LMLO and LCC):



It also looks for asymmetries between views from each side, for example, LMLO and RMLO:



The algorithm combines the results of these various analyses, analyzes the resulting cluster and context data, and employs statistical pattern recognition against the training database to determine the ranking for each of the possible clusters. It then selects the Calc marks that best meet the algorithm criteria (mark capping), and applies the selected operating point, thereby limiting the number of marked features.

Finally, if the algorithm determines that a selected Calc mark is coincident with a Mass mark, then the marks are converted into a Malc mark.

For more information see ‘2.3. Image and Case Processing’.

3.8. Detecting Masses

To detect masses, the ImageChecker algorithm performs a series of analyses.

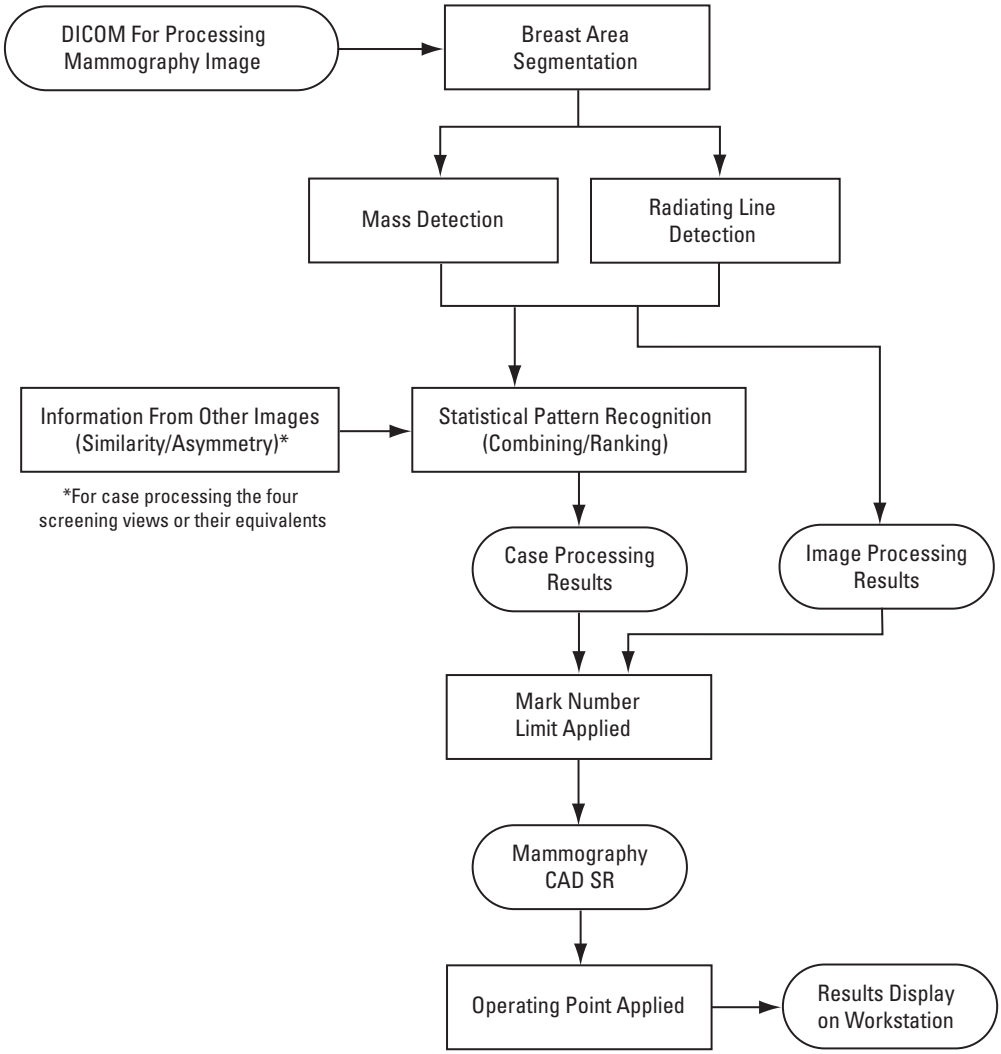
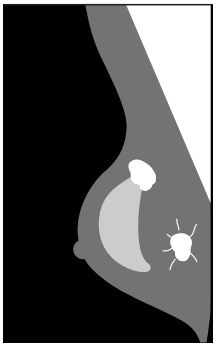

DICOM For Processing Mammography Image
Breast Area Segmentation
Mass Detection
Radiating Line Detection
Information From Other Images (Similarity/Asymmetry)*
Statistical Pattern Recognition (Combining/Ranking)
*For case processing the four screening views or their equivalents
Case Processing Results
Image Processing Results
Mark Number Limit Applied
Mammography CAD SR
Operating Point Applied
Results Display on Workstation

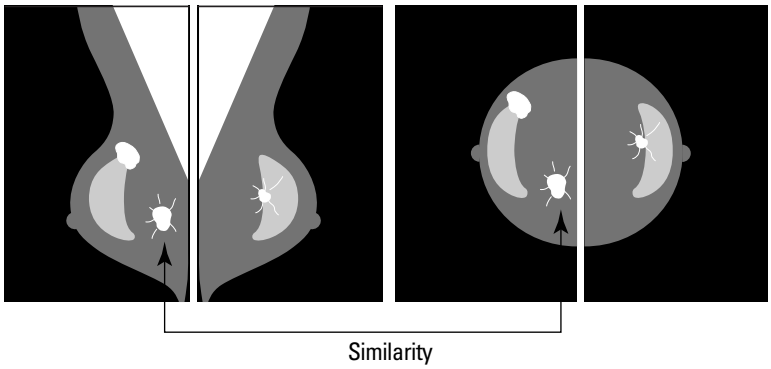
Image Processing for Masses



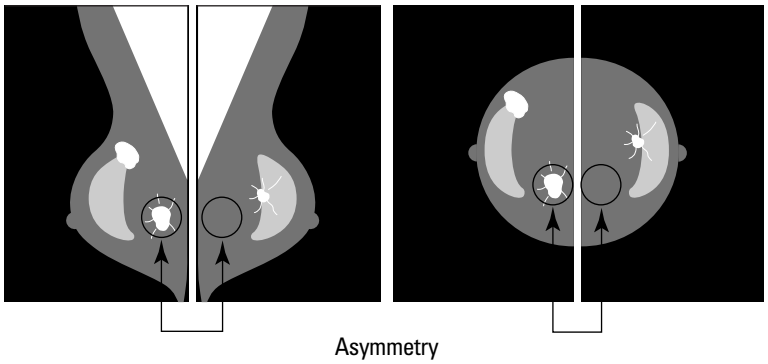
For each image, the algorithm uses patented technology to segment the breast. It then identifies masses by evaluating structures based on their density, shape, and margin characteristics. It also searches for structures appearing as radiating lines, and, if they are present, the degree of spiculation.

Case Processing for Masses

In addition to processing images individually, the ImageChecker algorithm selects up to four images that represent the screening views – RCC, LCC, RMLO, and LMLO (or their equivalents). The algorithm reviews the findings from each image and looks for similarities in the findings by comparing complementary orthogonal views (for example, LMLO and LCC):



It also looks for asymmetries between views from each side, for example, LMLO and RMLO:



The algorithm then runs the resulting data against the training database to determine the ranking for each of the possible masses. Finally, the algorithm either marks or does not mark the masses, based on the ranking and operating point.

The algorithm combines the results of these various analyses, analyzes the resulting cluster and context data, and employs statistical pattern recognition against the training database to determine the ranking for each of the possible clusters. It then selects the Calc marks that best meet the algorithm criteria (mark capping), and applies the selected operating point, thereby limiting the number of marked features.

Finally, if the algorithm determines that a selected Mass mark is coincident with a Calc mark, then the marks are converted into a Malc mark.

For more information see '2.3. Image and Case Processing'.

3.9. CAD Operating Points

ImageChecker allows each site to choose between three different operating points (i.e., CAD algorithm thresholds). You can choose a different operating point for calcifications than for masses, which provides a total of nine options for operating point combinations. The operating points are summarized below:

- **Operating point 0** trades off a lower false-mark rate for a lower overall sensitivity. This operating point is suited for sites that prefer the system to display the fewest false marks.
- **Operating point 1** represents a balanced intermediate point. Improvements in the algorithm have allowed points 0 and 2 to be set quite far apart, and some sites may want balanced behavior from the CAD algorithm.
- **Operating point 2** focuses on sensitivity. It gives the best performance for marking regions of interest (i.e., CAD sensitivity), with a higher false-mark rate. It is suited for sites that want the system to be as sensitive as possible, regardless of the higher false-positive mark rate.

For example, if you want high sensitivity for calcifications but a moderate balance between sensitivity and false positives for masses, choose operating point 2 for calcifications and operating point 1 for masses.

Each system is shipped with a default set of operating points for both masses and calcifications. You can discuss the choices that are right for your site with your Applications Specialist or, if you would like to change configurations, contact your Hologic | R2 Technical Service Representative.

The table below gives the sensitivity and false-mark rate values for the three operating points for ImageChecker software version 9.1, as measured on Hologic | R2's large *film* test database of biopsy-proven malignancies and confirmed normal cases for the four screening views (RCC, LCC, RMLO, and LMLO).

Operating Point:	0	1	2
Calcification Cases (n = 588)			
Mean Sensitivity[1]	95%	96%	97%
95% Confidence Interval	93.1–96.7%	94.0–97.2%	95.5–98.3%
Mass Cases (n = 767)			
Mean Sensitivity[1]	83%	88%	90%
95% Confidence Interval	79.8–85.2%	85.6–90.2%	87.7–92.0%
Overall (n = 1355)			
Mean Sensitivity[1]	88%	91%	93%
95% Confidence Interval	86.2–90.0%	89.7–92.7%	91.5–94.3%
False-Positive Marks[2]			
Calcification FP/Image	0.09	0.12	0.16
Mass FP/Image	0.17	0.25	0.35
Total False-Positive Marks/Case	1.0	1.5	2.0
Specificity[2]	48.3%	35.1%	24.5%
95% Confidence Interval	43.7–53.0%	30.6–39.5%	20.5–28.5%

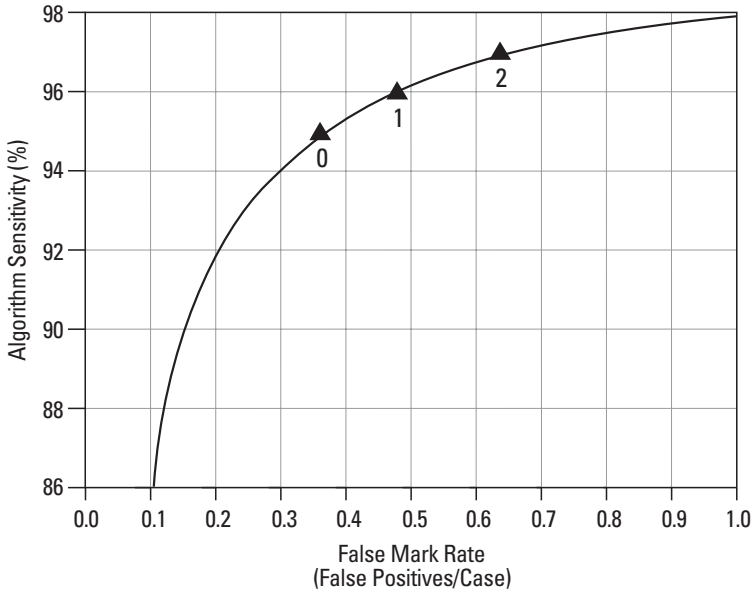
1. 'Sensitivity' refers only to the sensitivity of the CAD algorithm, not to the sensitivity of the radiologist using the device.

2. 'False-Positive' and 'Specificity' data were developed from a review of 445 confirmed normal cases (defined as those with a subsequent normal screening study). 'FP/Image' refers to the average number of false-positive marks per image measured on normal cases. 'Specificity' refers to the percentage of normal cases that, when processed, show no CAD marks.

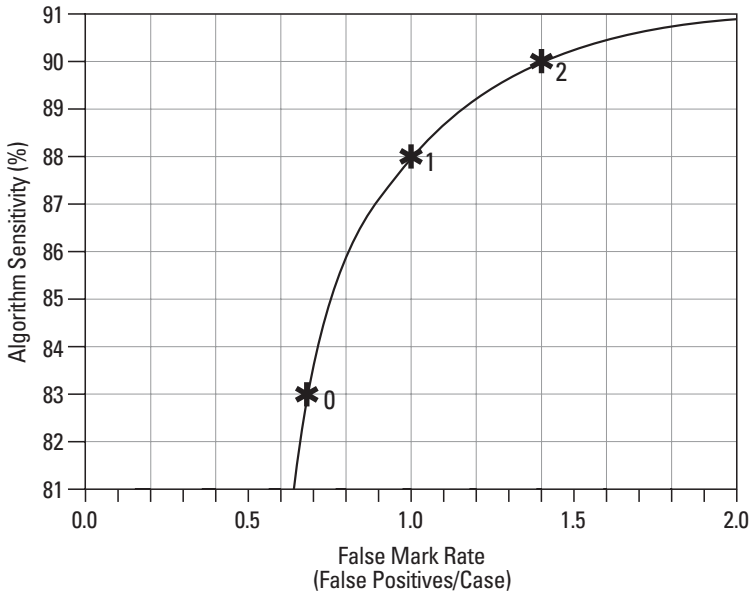
⚠ ***Note:*** *Earlier versions of the ImageChecker algorithm (before version 8.0) produce slightly different performance results. For further information, see the manuals provided with those systems.*

To determine false-mark rates, Hologic | R2 processes normal screening cases (defined as those with a subsequent normal screening study) through the ImageChecker software and measures the number of false marks per image. More extraordinary screening cases, such as those with additional views, and or those from diagnostic studies, may have a very different make-up of images and, as such, may produce results that fall outside the measured normal case mark rate. Since the mark rate is measured per image, a larger number of images in a case should correspond on average with a higher total mark count for that case. While clinical experience demonstrates some variation in mark rates, Hologic | R2 has not found the false-mark rate to vary dramatically when averaged over a large number of cases.

The following graphs shows plots of algorithm sensitivity vs. false-mark rate based on cases with the four screening views, with data points for each of the three operating points.



Calcification Performance



Mass Performance

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